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| TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 | | ATTORNEY'S DOCKET NUMBER 017191.0049 |
| INTERNATIONAL APPLICATION NO. PCT/US2004/024881 | INTERNATIONAL FILING DATE 29 July 2004 | U.S. APPLICATION NO. (if known, see 37 CFR 1.52) 10/574862 |
| TITLE OF INVENTION MONOCLONAL ANTIBODIES FOR DETECTION OF URINARY TRYPSIN INHIBITORS | | PRIORITY DATE CLAIMED 16 October 2003 |
| APPLICANT(S) FOR DO/EO/US Bayer Healthcare LLC | | |
| Applicant herewith submits to the United States Designated/Elected (DO/EO/US) the following items and other information: | | |
| <p>1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371.</p> <p>2. <input type="checkbox"/> This is a SECOND submission of items concerning a submission under 35 U.S.C. 371.</p> <p>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</p> <p>4. <input type="checkbox"/> The US has been elected (Article 31).</p> <p>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))</p> <p>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</p> <p>b. <input type="checkbox"/> has been communicated by the International Bureau.</p> <p>c. <input checked="" type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</p> <p>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).</p> <p>a. <input type="checkbox"/> is attached hereto.</p> <p>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</p> <p>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(2))</p> <p>a. <input type="checkbox"/> are attached hereto (required only if no communicated by the International Bureau).</p> <p>b. <input type="checkbox"/> have been communicated by the International Bureau.</p> <p>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</p> <p>d. <input type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p> <p>Items 11 to 20 below concern document(s) or information included:</p> <p>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input checked="" type="checkbox"/> An assignment document.</p> <p>13. <input checked="" type="checkbox"/> A preliminary amendment.</p> <p>14. <input checked="" type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input checked="" type="checkbox"/> A power of attorney and/or change of address letter.</p> <p>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825.</p> <p>18. <input checked="" type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p> | | |

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

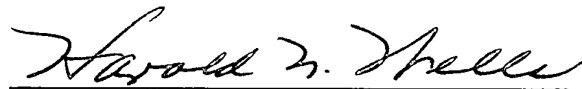
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|---|--------------|---|---------|---------------------------|----|
| U.S. APPLICATION NO. (if known, see 37 CFR 1.5) | | INTERNATIONAL APPLICATION NO. | | ATTORNEY'S DOCKET NUMBER | |
| 10/574862 | | PCT/US2004/024881 | | 017191.0049 | |
| 20. Other items or information: Declaration Under 37 CFR 1.132 including attachments; Declaration for Utility or Design Patent Application; Certificate of Express Mail; postcard | | | | | |
| The following fees have been submitted | | | | CALCULATIONS PTO USE ONLY | |
| 21. <input checked="" type="checkbox"/> Basic national fee (37 CFR 1.49(a)).....\$300 | | | | \$300.00 | |
| 22. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.49(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).....\$0 All other situations.....\$200 | | | | \$200.00 | |
| 23. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).....\$0 Search fee (37 CFR 1.44(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority.....\$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB.....\$400 All other situations.....\$500 | | | | \$400.00 | |
| TOTAL OF 21, 22 AND 23 = | | | | 900.00 | |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.82(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. | | | | | |
| Total Sheets | Extra Sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | RATE | | |
| - 100 = | /50 = | | x \$250 | \$ | |
| Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)). | | | | \$ | |
| CLAIMS | NUMBER FILED | NUMBER EXTRA | RATE | \$ | |
| Total claims | 37 - 20 = | 17 | x \$50 | \$850.00 | |
| Independent claims | 3 - 3 = | 0 | x \$200 | \$0.00 | |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable) | | | x \$360 | 360.00 | |
| TOTAL OF ABOVE CALCULATIONS = | | | | \$1,210.00 | |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2. | | | | | |
| SUBTOTAL = | | | | \$2,110.00 | |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). + | | | | \$ | |
| TOTAL NATIONAL FEE = | | | | \$ | |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property + | | | | \$ | |
| TOTAL FEES ENCLOSED = | | | | \$2,110.00 | |
| | | | | Amount to be refunded: | \$ |
| | | | | Amount to be charged: | \$ |

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- a. ☒ A check in the amount of \$2,110.00 to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 110404. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:



SIGNATURE

HAROLD N. WELLS

NAME

26,044

REGISTRATION NUMBER

10/574862

APR 06 2006
PCT/PTO

CERTIFICATE OF EXPRESS MAIL

I hereby certify that the following documents are being deposited with the United States Postal Service "EXPRESS MAIL POST OFFICE TO ADDRESSEE" service under 37 C.F.R. 1.10 on the date indicated below and addressed to: MAIL STOP PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313.

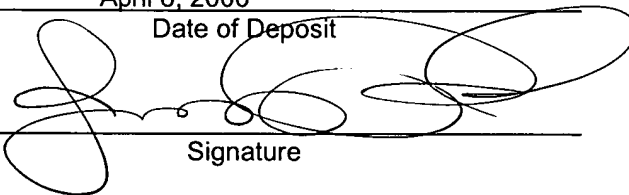
371 Transmittal Form; Preliminary Amendment; copy of WO 2005/040222; copy of specification including drawings; Application Data Sheet; Declaration under 1.132 including attachments; copy of International Search Report; copy of International Preliminary Examination Report; Power of Attorney and Correspondence Address Form; Statement Under 37 CFR 3.73(b); Declaration for Utility or Design Patent Application; copy of Assignment Recordal Statement; copy of Assignment Cover Sheet and copy of Assignment document; Certificate of Express Mail; check; Acknowledgment postcard.

EV 649 544 755 US

Express Mail Receipt Number

April 6, 2006

Date of Deposit


Signature